Paper No. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte GLENN J. GORMLEY, KEITH D. KAUFMAN, ELIZABETH STONER and JOANNE WALDSTREICHER

Appeal No. 2004-0543
Application No. 10/010,678

ON BRIEF

Before SCHEINER, MILLS and GRIMES, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 28-37, the only claims remaining. Claims 28, 30, 33 and 36 are representative:

28. A method of treating androgenic alopecia comprising transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor.

30. The method according to claim 28, wherein the 5alpha-reductase 2 inhibitor is transdermally administered by a transdermal skin patch.

33. A method of treating androgenic alopecia comprising transdermally administering to a person in need of such treatment a therapeutically effective amount of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one.

36. A transdermal skin patch comprising a therapeutically effective amount of a 5alpha-reductase 2 inhibitor.

The references relied on by the examiner are:

Goldman	5,407,944	Apr. 18, 1995
Rasmusson et al. (Rasmusson)	EP 0 285 382	Oct. 5, 1988

Claims 28, 29 and 31-34 stand rejected under 35 U.S.C. § 102(b) as anticipated by Rasmusson, while claims 30 and 35-37 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Rasmusson and Goldman.

For the reasons which follow, we reverse the rejection of claims 28, 29 and 31-34 under 35 U.S.C. § 102(b); vacate the rejection of claims 30 and 35-37 under 35 U.S.C. § 103; and enter a new ground of rejection against claims 28-37 under the provisions of 37 CFR § 41.50(b).[1]

DISCUSSION

Anticipation by Rasmusson

According to the examiner, Rasmusson describes treating androgenic alopecia "using topical 5 alpha reductase inhibitors (e.g. 17-beta-N-monosubstituted-carbamoyl-4-aza-5alpha reductase inhibitors [like 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one]) . . . in the form of cream, lotion or ointment" (Answer, page 4) and thus meets "all the critical elements required by [claims 28, 29 and 31-34]" (id., page 5).

There is no dispute that Rasmusson describes the 5-alpha reductase inhibitors required by the present claims, rather, the issue is whether Rasmusson's "topical" administration of the inhibitor meets the present requirement for "transdermal" administration.

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[1] The term "vacate," as applied to an action taken by an appellate tribunal, means to set aside or void. Black's Law Dictionary 1075 (abridged 6th ed. 1991). When the board vacates a rejection in favor of a new ground of rejection, the original rejection no longer exists. We emphasize that the board does not take an ultimate position on the correctness of an examiner's rejection when that rejection is vacated. See also Ex parte Zambrano, 58 USPQ2d 1312 (Bd.Pat.App. & Int. 2001).

Claims 28, 29 and 31-34 specifically require transdermal administration of the inhibitor. We agree with the examiner that "transdermal administration is broader than skin-patch administration" (Answer, page 8), but disagree with the examiner's assertion that "appellants prefer the claim language to be understood as 'use of [a] transdermal skin patch'" (id.).[2] Rather, appellants' position is essentially that "transdermal ('through-the-skin') administration constitutes a separate and distinct claim limitation from [ ] topical ('cutaneous') administration of 5alpha-reductase 2 inhibitors" (Brief, page 6), and "the two routes of administration are in fact not interchangeable" (id., page 7), because transdermal administration is systemic and continuous, while topical administration is local and intermittent (id., pages 7 and 8).

Appellants rely on two forms of evidence in support of their position: their original disclosure, and an excerpt from The Merck Manual.[3] With respect to their original disclosure, appellants argue that "the fact that [ ] transdermal administration and topical administration [are taught] in two different paragraphs [on page 6] suggests that the two routes of administration are not interchangeable" (Brief, page 7). Nevertheless, we find that there is some overlap between the two terms as they are used in the specification. That is, the specification teaches that "transdermal" administration is systemic and "continuous rather than intermittent" (Specification, page 7), but does not restrict

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[2] The examiner's interpretation of appellants' argument appears to stem from appellants' statement on page 7 of the Brief that their "original patent disclosure [(at page 6, lines 22-24 and 32-34)] associates topical administration with 'solution[s], cream[s], ointment[s], gel[s], lotion[s], shampoo[s] or aerosol formulation[s]' . . . [while] transdermal administration is linked to the use of transdermal skin patches only."

[3] The Merck Manual, Second Home Edition, Chapter 11, Drug Administration and Kinetics, Thomas N. Tozer, Ph.D., Drug Administration, Appendix I; submitted with appellants' Brief as Appendix II, and available at http:// www.merck.com/pubs/mmanual_home2/sec02/ch011/ch011b.htm .

"topical" administration to local or intermittent administration. As used in the specification, "topical" administration can also include systemic administration: for example, the specification teaches that "5α-reductase 2 inhibitor compounds . . . can be administered in a wide variety of therapeutic dosage forms in conventional vehicles for systemic administration. For example, the compounds can be administered in such oral dosage forms as tablets, capsules [ ], pills, powders, granules, elixirs, tinctures, solutions, suspensions, syrups and emulsions. Likewise, they may also be administered in intravenous [form], intraperitoneal [form], subcutaneous [form], topical [form] with or without occlusion, or intramuscular form . . ." (Page 6, emphasis added).

Similarly, The Merck Manual teaches that drugs "may be applied to the skin (cutaneously) for a local (topical) or bodywide (systemic) effect; or delivered through the skin by a patch (transdermally) for a systemic effect" (Appendix II, page 1). Under the heading "Cutaneous Route," the manual indicates that "[d]rugs applied to the skin are usually used for their local effects and thus are most commonly used to treat superficial skin disorders . . . depending on the consistency of [ ] inactive substances, the formulation may be an ointment, a cream, a lotion, a solution, a powder or a gel" (id., page 3, emphasis added). Under the heading "Transdermal Route," the manual teaches that "[s]ome drugs are delivered bodywide through a patch on the skin. These drugs, sometimes mixed with a chemical (such as alcohol) that enhances penetration of the skin, pass through the skin to the bloodstream without injection. Through a patch, the drug can be delivered slowly and continuously for many hours or days . . . As a result, levels of a drug in the blood can be kept relatively constant" (id., pages 3-4).

Having reviewed the evidence of record, we find that the terms transdermal administration and topical administration are not always mutually exclusive. That is, while transdermal administration of a substance results in systemic administration ("through-the-skin" administration), topical administration can result in strictly local, or systemic administration – depending upon the carrier used. In other words, topical administration can, in some circumstances, include transdermal administration. Thus, the issue comes down to what Rasmusson means by "topical" administration.

Rasmusson describes "a method of treating the hyperandrogenic conditions of androgenic alopecia, including male pattern alopecia, acne vulgaris, seborrhea, and female hirsutism by topical administration, and a method of treating all of the above conditions as well as benign prostatic hypertrophy, by systemic administration" of 5 alpha reductase inhibitors (page 6, emphasis added). According to Rasmusson, "topical pharmaceutical compositions may be in the form of a solution, cream, ointment, gel, lotion, shampoo or aerosol formulation adapted for application to the skin" (id.), while "the active ingredient for use in the treatment of benign prostatic hypertrophy can be administered in a wide variety of therapeutic dosage forms in conventional vehicles for systemic administration, as, for example, by oral administration in the form of tablets, capsules, solutions or suspensions, of [sic] by intravenous injection" (id.).

We find (1) that Rasmusson's use of the term "topical" administration does not include systemic administration, and therefore, does not include "transdermal" administration; and (2) that none of the "vehicles for systemic administration" described in the reference are suitable for transdermal administration. Therefore, we conclude that Rasmusson does not anticipate the claimed invention, and the rejection of claims 28, 29 and 31-34 under 35 U.S.C. § 102(b) is reversed.

Unpatentability over Rasmusson and Goldman

Claims 30 and 35-37 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Rasmusson and Goldman. The underlying premise of the rejection is that Rasmusson describes transdermal administration of a 5α-reductase 2 inhibitor, and lacks only a description of a transdermal skin patch; the examiner relies on Goldman to make up this deficiency.

As discussed above, we do not agree that Rasmusson describes transdermal administration of a 5α-reductase 2 inhibitor. On the other hand, we agree with the examiner that Goldman is relevant to the claimed invention, but for reasons somewhat different than those of the examiner. Therefore, we vacate the examiner's rejection of claims 30 and 35-37 and enter the following new ground of rejection under the provisions of 37 CFR § 41.50(b).

NEW GROUND OF REJECTION UNDER 37 CFR § 41.50(b)

Claims 28-37 are rejected under 35 U.S.C. § 103(a) as unpatentable over Goldman. Claim 28 is directed to a method of treating androgenic alopecia comprising transdermally administering a 5-α-reductase inhibitor; claim 30 specifies administration by transdermal skin patch; claim 33 specifies that the 5-α-reductase inhibitor is 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one), otherwise known as "finasteride;" claim 36 is directed to a skin patch comprising a 5-α-reductase inhibitor.

Goldman teaches that androgenic alopecia/male pattern baldness can be treated topically or systemically with a combination of three agents: a vasodilator; an estradiol; and 5-α-reductase inhibitor (column 2, lines 42-46; column 6, lines 5-9). "A highly preferred inhibitor of . . . 5-α-reductase for use in [Goldman's] compositions and

methods" (column 5, lines 43-44), indeed the only 5-α-reductase inhibitor specifically mentioned, is finasteride (column 5, lines 43-62). While "each agent of the combination need not be administered in the same manner" (column 2, lines 65-67), "in a highly preferred embodiment the selected agents are administered from a single vehicle in unit dosage form, including tablet, capsule, and transdermal patches or preparation" (column 3, lines 7-10).

While Goldman does not specifically describe incorporating a 5-α-reductase inhibitor into a transdermal skin patch and using the patch to treat androgenic alopecia, he explicitly suggests doing just that. Moreover, Goldman identifies finasteride as a "highly preferred" 5-α-reductase inhibitor for this purpose. It would have been obvious for one skilled in the art to have treated androgenic alopecia by transdermal administration of a pharmaceutical preparation, e.g., a transdermal skin patch, comprising a 5-α-reductase inhibitor, e.g., finasteride, in view of Goldman's explicit suggestions.

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen Prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request Rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

REVERSED; VACATED; 37 CFR § 41.50(b)

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